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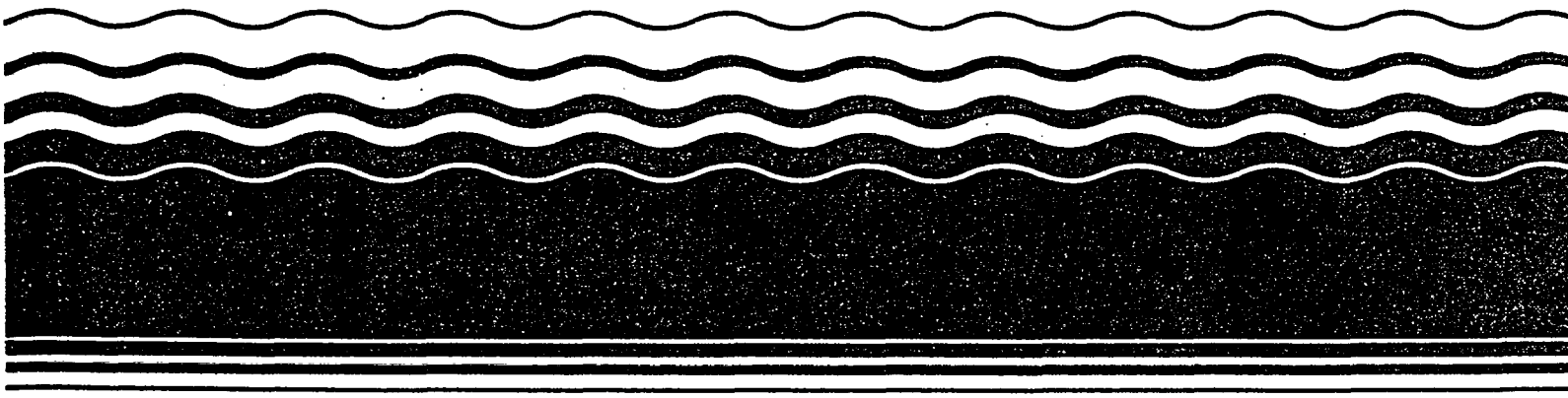
Superfund

EPA

Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA

Interim Final



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Chapter 1
Introduction

1.1 Purpose of the RI/FS

The remedial investigation and feasibility study (RI/FS) process as outlined in this guidance represents the methodology that the Superfund program has established for characterizing the nature and extent of risks posed by uncontrolled hazardous waste sites and for evaluating potential remedial options. This approach should be viewed as a dynamic, flexible process that can and should be tailored to specific circumstances of individual sites; it is not a rigid step-by-step approach that must be conducted identically at every site. The project manager's central responsibility is to determine how best to use the flexibility built into the process to conduct an efficient and effective RI/FS that achieves high quality results in a timely and cost-effective manner. A significant challenge project managers face in effectively managing an RI/FS is the inherent uncertainties associated with the remediation of uncontrolled hazardous waste sites. These uncertainties can be numerous, ranging from potential unknowns regarding site hydrogeology and the actual extent of contamination, to the performance of treatment and engineering controls being considered as part of the remedial strategy. While these uncertainties foster a natural desire to want to know more, this desire competes with the Superfund program's mandate to perform cleanups within designated schedules.

The objective of the RI/FS process is not the unobtainable goal of removing *all* uncertainty, but rather to gather information sufficient to support an informed risk management decision regarding which remedy appears to be most appropriate for a given site. The appropriate level of analysis to meet this objective can only be reached through constant strategic thinking and careful planning concerning the essential data needed to reach a remedy selection decision. As hypotheses are tested and either rejected or confirmed, adjustments or choices as to the appropriate course for further investigations and analyses are required. These choices, like the remedy selection itself, involve the balancing of a wide variety of factors and the exercise of best professional judgment.

1.2 Purpose of the Guidance

This guidance document is a revision of the U.S. Environmental Protection Agency's (EPA) *Guidance on Remedial Investigations Under CERCLA* (May 1985) and *Guidance on Feasibility Studies Under CERCLA* (June 1985). These guidances have been consolidated into a single document and revised to (1) reflect new emphasis and provisions of the Superfund Amendments and Reauthorization Act (SARA), (2) incorporate aspects of new or revised guidance related to aspects of remedial investigations and feasibility studies (RI/FSs), (3) incorporate management initiatives designed to streamline the RI/FS process, and (4) reflect experience gained from previous RI/FS projects.

The purpose of this guidance is to provide the user with an overall understanding of the RI/FS process. Expected users include EPA personnel, State agencies responsible for coordinating or directing activities at National Priorities List (NPL) sites, potentially responsible parties (PRPs), Federal facility coordinators, and consultants or companies contracted to assist in RI/FS-related activities at NPL sites. This guidance describes the general procedures for conducting an RI/FS.[1] Where specific guidance is currently available elsewhere, the RI/FS guidance will simply highlight the key points or concepts as they relate to the RI/FS process and refer the user to the other sources for additional details.

1.3 Overview of CERCLA Reauthorization

SARA was signed by the President on October 17, 1986, to amend the Comprehensive Environmental Response, Compensation, and Liability Act of 1980

[1] This guidance document does not typically address differences in the general procedures (e.g., work plan preparation, reporting requirements) between a Fund-financed and PRP-conducted RI/FS, and the flexibility discussed for certain activities may not pertain to a PRP-conducted RI/FS. Therefore, when PRPs are conducting an RI/FS, this guidance document must be used in conjunction with the "Interim Guidance on PRP Participation in the RI/FS Process" (see Appendix A).

Chapter 2
Scoping the RI/FS

2.1 Introduction

Scoping is the initial planning phase of site remediation and is begun, at least informally, by the lead agency's RPM as part of the funding allocation and planning process. The lead and support agencies should meet and, on the basis of available information, begin to (1) identify the types of actions that may be required to address site problems; (2) identify whether interim actions are necessary or appropriate to mitigate potential threats, prevent further environmental degradation, or rapidly reduce risks significantly, and (3) identify the optimal sequence of site actions and investigative activities.

Once the lead and support agencies initially agree on a general approach for managing the site, the next step is to scope the project(s) and develop specific project plans. Project planning is done to:

- Determine the types of decisions to be made
- Identify the type and quality of data quality objectives (DQOs) needed to support those decisions
- Describe the methods by which the required data will be obtained and analyzed
- Prepare project plans to document methods and procedures

The activities described above relate directly to the establishment of DQOs – statements that specify the type and quality of the data needed to support decisions regarding remedial response activities. The establishment of DQOs is discussed in detail in *Data Quality Objectives for Remedial Response Activities* (U.S. EPA, March 1987, hereafter referred to as the *DQO Guidance*).

The ability to adequately scope a specific project is closely tied to the amount and quality of available information. Therefore, it is important to note that the scope of the project and, to some extent the specific project plans, are developed iteratively (i.e., as new information is acquired or new decisions are made, data requirements are reevaluated and, if appropriate, project plans are modified). In this way, scoping helps to focus activities and streamline the RI/FS, thereby preventing needless expenditures and loss of time in unnecessary sampling and analyses.

Figure 2-1 shows the key steps in the scoping process.[1]

2.2 Project Planning

Once a general site management approach has been agreed upon, planning can begin for the scope of a specific project. The specific activities conducted during project planning include:[2]

- Meeting with lead agency, support agency, and contractor personnel to discuss site issues and assign responsibilities for RI/FS activities
- Collecting and analyzing existing data to develop a conceptual site model that can be used to assess both the nature and the extent of contamination and to identify potential exposure pathways and potential human health and/or environmental receptors
- Initiating limited field investigations if available data are inadequate to develop a conceptual site model and adequately scope the project
- Identifying preliminary remedial action objectives and likely response actions for the specific project
- Preliminarily identifying the ARARs expected to apply to site characterization and site remediation activities
- Determining data needs and the level of analytical and sampling certainty required for additional data

[1] See Appendix A for a delineation of responsibilities between the lead agency and the PRPs during the scoping process.

[2] For a PRP-lead RI/FS the PRPs are typically responsible for these activities except for conducting community interviews. This responsibility rests with the lead agency. Specific activities performed by the PRPs during scoping are determined during the negotiation period and should be specified in the agreement between the PRPs and the lead agency.

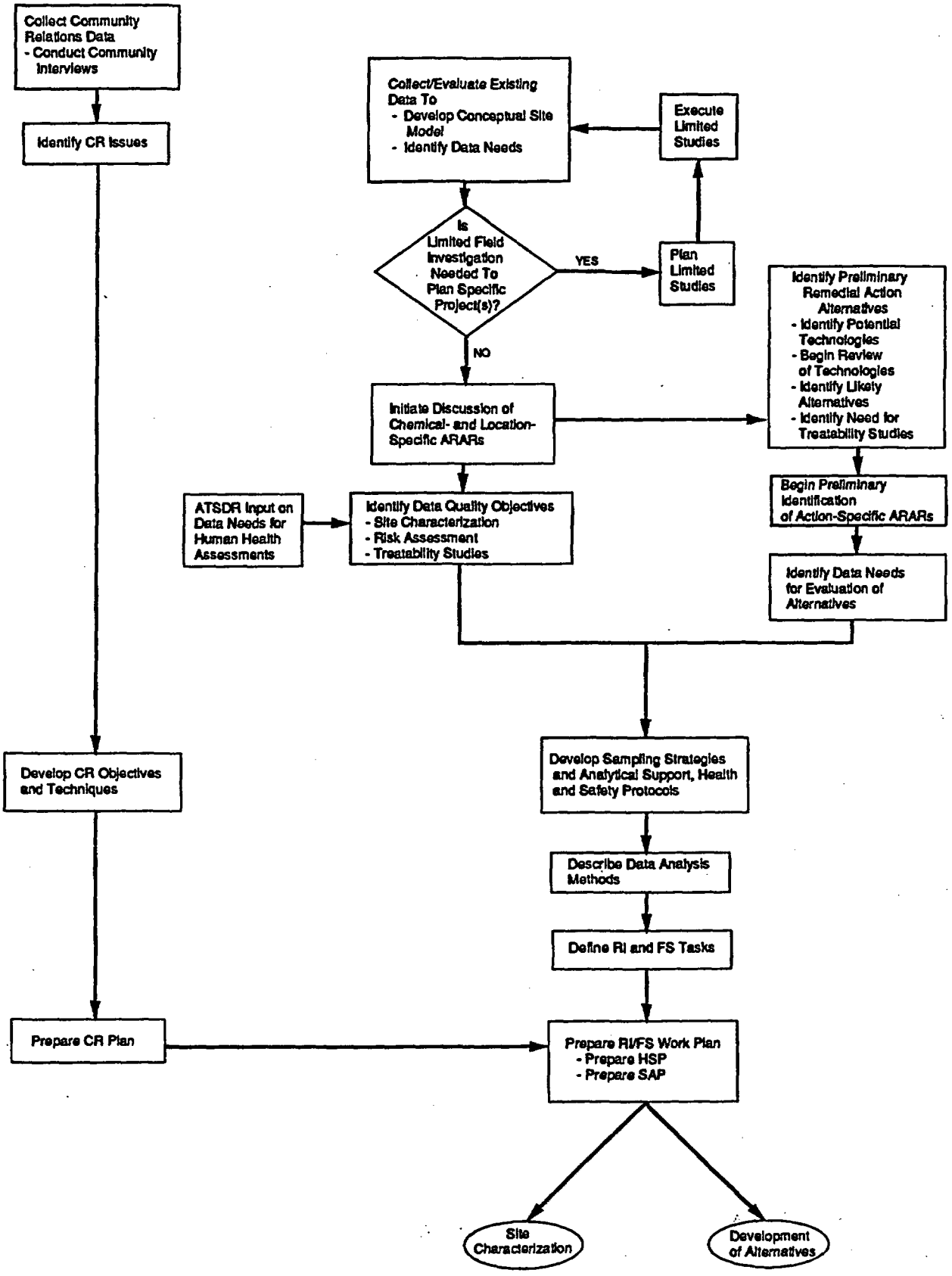


Figure 2-1. Scoping.

if currently available data are inadequate to conduct the FS

- Identifying the need and the schedule for treatability studies to better evaluate potential remedial alternatives

- Designing a data collection program to describe the selection of the sampling approaches and analytical options. (This selection is documented in the SAP, which consists of the FSP and QAPP elements.)

- Developing a work plan that documents the scoping process and presents anticipated future tasks

- Identifying and documenting health and safety protocols required during field investigations and preparing a site health and safety plan

- Conducting community interviews to obtain information that can be used to develop a site-specific community relations plan that documents the objectives and approaches of the community relations program

2.2.1 *Conduct Project Meeting*

To begin project planning, a meeting should be held involving key management from the lead and support agencies. The purpose of this meeting is to allow key personnel to become involved in initial planning decisions and give them the opportunity to discuss any special concerns that may be associated with the site. Furthermore, this meeting should set a precedent for the involvement of key personnel periodically throughout the project. Additional attendees should include contractor personnel who will be conducting the RI/FS and performing the risk assessment, Natural Resource Trustee representatives, when applicable, and individuals with prior experience at the site [e.g., the field investigation team (FIT)] or other similar sites who may be able to provide additional insight into effective techniques for addressing potential site problems.

2.2.2 *Collect and Analyze Existing Data*

Before the activities necessary to conduct an RI/FS can be planned, it is important to compile the available data that have previously been collected for a site. These data can be used to determine the additional work that needs to be conducted both in the field and within the community. A thorough search of existing data should help avoid duplication of previous efforts and lead to a remedial investigation that is more focused and, therefore, more efficient in its expenditure of resources.

Information describing hazardous waste sources, migration pathways, and human and environmental receptors for a given site is available from many sources. Some of the more useful sources are listed in Table 2-1. Site investigation (SI) data[3] gathered in the hazard ranking process (the process by which a site is listed on the NPL) may be located in files maintained by the EPA Regional offices, the FIT, the technical assistance team (TAT), contractors, and the state.

Data relating to the varieties and quantities of hazardous wastes disposed of at the site should be compiled. The results from any previous sampling events should be summarized in terms of physical and chemical characteristics, contaminants identified, and their respective concentrations. Results of environmental sampling at the site should be summarized, and evidence of soil, ground water, surface water, sediment, air, or biotic contamination should be documented. If available, information on the precision and accuracy of the data should be included.

Records of disposal practices and operating procedures at the site, including historical photographs, can be reviewed to identify locations of waste materials onsite, waste haulers, and waste generators. If specific waste records are absent, waste products that may have been disposed of at the site can be identified through a review of the manufacturing processes of the waste generators.

A summary of existing site-specific and regional information should be compiled to help identify surface, subsurface, atmospheric, and biotic migration pathways. Compiled information should include geology, hydrogeology, hydrology, meteorology, and ecology. Regional information can help to identify background soil, water, and air quality characteristics. Data on human and environmental receptors in the area surrounding the site should be compiled. Demographic and land use information will help identify potential human receptors. Residential, municipal, or industrial wells should be located, and surface water uses should be identified for surrounding areas and areas downstream of the site.

Existing information describing the common flora and fauna of the site and surrounding areas should be collected. The location of any threatened, endangered, or rare species, sensitive environmental areas, or critical habitats on or near the site should be identified. Available results from any previous biological testing should be compiled to document

[3] The expanded site investigation (ESI) conducted by the pre-remedial program will provide valuable data (e.g., geophysics, surveys, well inventories) and should serve as an important source of information during the scoping process for establishing the hypotheses to be tested concerning the nature and extent of contamination.

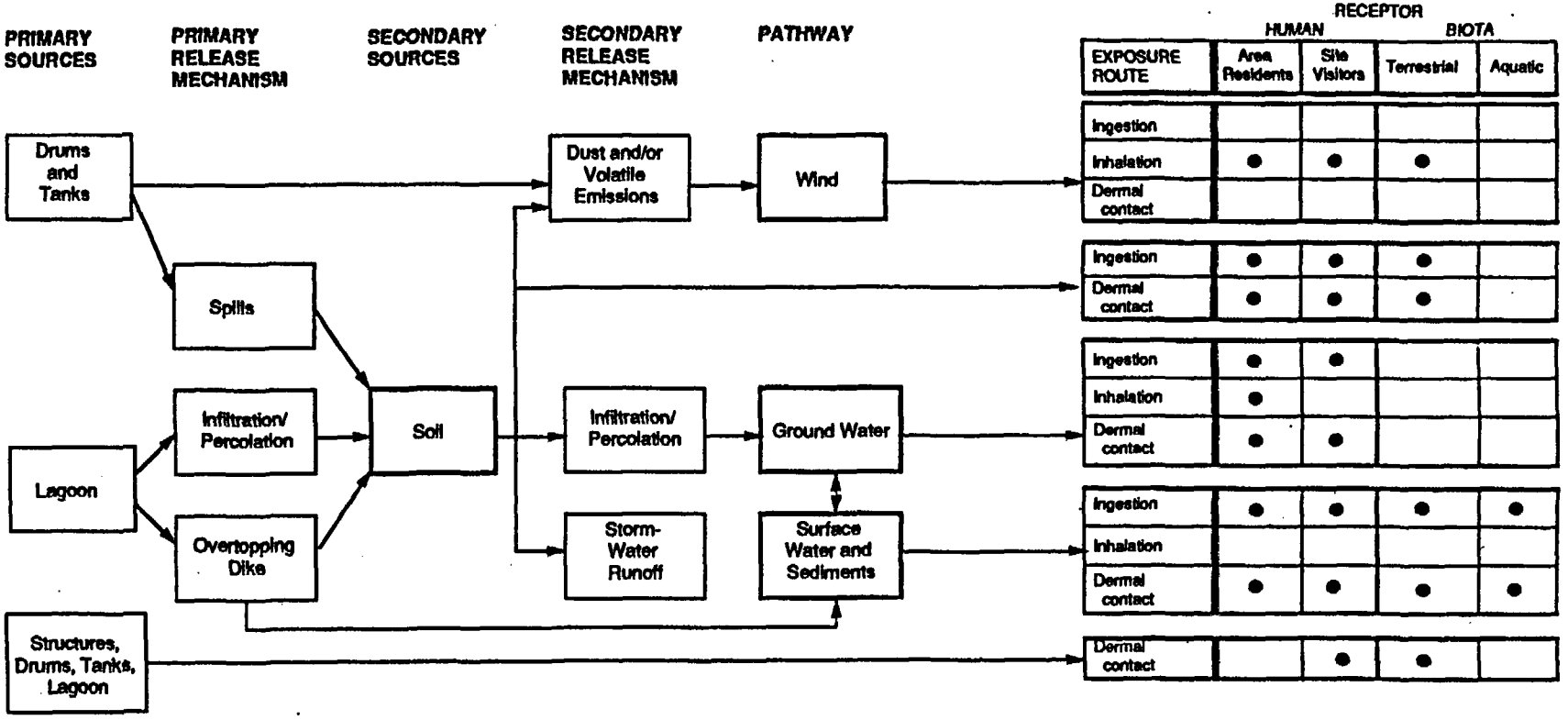


Figure 2-2. Example Conceptual Site Model.

2.3.1 *Work Plan*

2.3.1.1 Purpose

The work plan documents the decision and evaluation made during the scoping process and presents anticipated future tasks. It also serves as a valuable tool for assigning responsibilities and setting the project's schedule and cost. Information on planning work for lead agency staff may be found in the *Superfund Federal-Lead Remedial Project Management Handbook* (U.S. EPA, December 1986); and the *Superfund State-Lead Remedial Project Management Handbook* (U.S. EPA, December 1986). The primary user of the RI/FS work plan is the lead agency for the site (usually either the EPA Region or the appropriate federal or state agency) and the project team that will execute the work. Secondary users of the work plan include other groups or agencies serving in a review capacity, such as EPA Headquarters and local government agencies. The work plan is usually made available for public comment (often in conjunction with a public meeting) and is placed in the Administrative Record.

2.3.1.2 Preparation

The work plan presents the initial evaluation of existing data and background information performed during the scoping process, including the following:

- An analysis and summary of the site background and the physical setting
- An analysis and summary of previous responses
- Presentation of the conceptual site model, including an analysis and summary of the nature and extent of contamination; preliminary assessment of human health and environmental impacts; and the additional data needed to conduct the baseline risk assessment
- Preliminary identification of general response actions and alternatives and the data needed for the evaluation of alternatives

The work plan also defines the scope and objectives of RI/FS activities to the extent possible. The scope of the RI site characterization should be documented in the work plan, with detailed descriptions provided in the SAP. Later tasks will usually be scoped in less detail, pending the acquisition of more complete data about the site.

The initial work plan is prepared prior to the RI site characterization.[7] Because the RI/FS process is dynamic and iterative, the work plan or supplemental plans, such as the QAPP and the FSP, can be modified during the RI/FS process to incorporate new information and refined project objectives. The work plan should be revised, if necessary, before (1) additional iterations of site characterization activities, and (2) treatability investigations. On federal-lead sites, a work plan revision request (WPRR) is submitted for approval of any significant changes to the budget schedule, or scope. EPA has found technical directive memorandums (TDMs) to be useful for decreasing administrative time when the proposed work plan changes do not affect the total budget or schedule.

2.3.1.3 Work Plan Elements

Five elements (Introduction, Site Background and Physical Setting, Initial Evaluation, Work Plan Rationale, and RI/FS Tasks) typically are included in a work plan. These elements are described in Appendix B.

Among the elements to be included is the specification of RI/FS tasks. For federal-lead sites, 14 standard tasks have been defined to provide consistent reporting and allow more effective monitoring of RI/FS projects. Figure 2-4 shows these tasks and their relationship to the phases of an RI/FS, and detailed task definitions are included in Appendix B. Although RI/FSs that are not federal-lead projects are not required to use these standard tasks, their use provides a valuable project management tool that allows for compilation of historical cost and schedule data to help estimate these tasks during project planning and management.

Project Management Considerations. Project management considerations may be specified in the work plan to define relationships and responsibilities for selected task and project management items. This specification is particularly useful when the lead agency is using extensive contractor assistance. The following project management considerations may be discussed in the work plan:

- Identification of staff (the lead agency's RPM, the PRP's project manager, the contractor, the contractor's site manager, and other team members)
- Coordination among the lead agency, the support agency, the PRPs and the contractors performing the work
- Coordination with other agencies (Typically, the lead agency's RPM is the focus for the coordination of all other agency and private participation in site activities and decisions.)

[7] In enforcement cases, PRPs are typically responsible for the development of the work plan (See Appendix A).

Table 2-2. Communication and Deliverables During Scoping

Information Needed	Purpose	Potential Methods of Information Exchange
Interim actions (if necessary)	For lead agency and contractor to identify actions that will abate immediate threat to public health or prevent further degradation of the environment; to obtain concurrence of support agency	Meeting Tech Memo Other
Limited field investigations (if necessary)	For lead agency and contractor to improve focus of RI and reduce time and cost; to obtain concurrence of support agency	Meeting Tech Memo Other
Summary of existing data; field studies conducted prior to FS; identification of preliminary remedial action alternatives	For lead agency and contractor to confirm need for field studies; for lead agency and contractor to plan data collection; to obtain support agency review and concurrence	Meeting Tech Memo Other
Documentation of quality assurance (QA) and field sampling procedures	For contractor to obtain lead agency review and approval; for lead agency to obtain support agency review and comment	SAP (FSP,QAPP)
Documentation of health and safety procedures	For contractor to obtain lead agency agreement that OSHA safety requirements are met	Health and safety plan
Documentation of all RI/FS tasks	For contractor to obtain lead agency review and approval; for lead agency to obtain support agency concurrence	Work plan

- Coordination of subcontractors, if any, and description of health and safety requirements and responsibilities
- Interface for federal-lead projects with the Contract Laboratory Program (CLP), if needed, to minimize sampling requirements by use of field screening, to schedule analyses well ahead of sampling trips, and to accurately complete CLP paperwork
- Cost control (including a description of procedures for contractors to report expenditures)
- Schedule control (including a description of schedule tracking methods and procedures for contractors to report activities to the lead agency)
- Identification of potential problems so that the RPM and site manager can develop contingency plans for resolution of problems during the RI/FS
- Evidentiary considerations, if needed, to ensure that project staff members are trained with regard to requirements for admissibility of the work in court

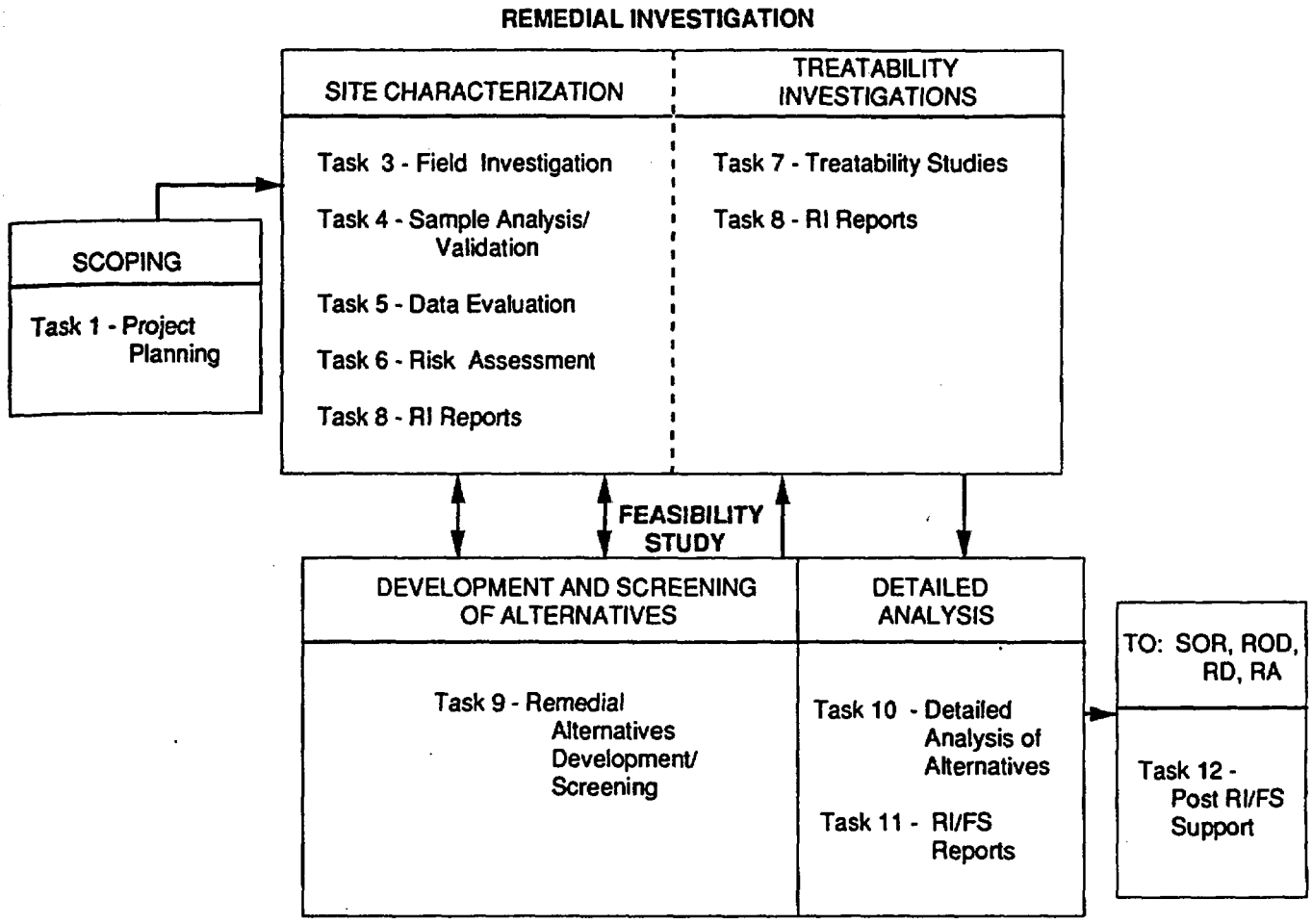
Cost and Key Assumptions. For federal-lead sites, the RI/FS work plan includes a detailed summary of projected labor and expense costs,[8] broken down by the 14 tasks listed in Figure 2-3 and described in Appendix B, and a description of the key assumptions required to make such a cost estimate. During scoping, more detailed costs typically are provided for the RI site characterization tasks than for later phases of the RI/FS. The less-detailed costs may be refined as field investigations progress and the nature and extent of site contamination is more fully understood.

RI/FS costs vary greatly among sites and are influenced by the following:

- The adequacy of existing data
- The size and complexity of the site
- The level of personnel protection required for onsite workers
- The number and depth of wells required and the types of subsurface conditions where wells will be installed
- The number and types of media sampled
- The number of samples required for each medium
- The need for support of enforcement activities
- The need for bench- or pilot-scale tests

Schedule. The anticipated schedule for the RI/FS is formulated on the basis of the scope of the project, including the identification of key activities and deliverable dates. As with cost, the scheduling of tasks varies among sites.

[8]The estimated RI/FS costs prepared by the RPM during the scoping process will form the basis for evaluating costs proposed by the contractor in the work plan and should help facilitate the control of project costs as the RI/FS proceeds. Cost estimates may not be required for State- and PRP-lead RI/FSs.



RI/FS WORK PLAN STANDARD TASKS

TASK	TITLE
1	Project Planning
2	Community Relations *
3	Field Investigation
4	Sample Analysis/ Validation
5	Data Evaluation
6	Risk Assessment
7	Treatability Study/ Pilot Testing
8	Remedial Investigation Reports
9	Remedial Alternatives Development/ Screening
10	Detailed Analysis of Alternatives
11	Feasibility Study (RI/FS) Reports
12	Post RI/FS Support
13	Enforcement Support *
14	Miscellaneous Support *

* Tasks that can occur in any Phase of the RI/FS

Figure 2-4. Relationship of RI/FS Tasks to Phased RI/FS Approach.

2.3.1.4 Report Format

The work plan should include the elements described in Appendix B. Table 2-3 provides a suggested format.

Table 2-3. Suggested RI/FS Work Plan Format

Executive Summary

1. Introduction
2. Site Background and Setting
3. Initial Evaluation
   - Types and volumes of waste present
   - Potential pathways of contaminant migration/preliminary public health and environmental impacts
   - Preliminary identification of operable units
   - Preliminary identification of response objectives and remedial action alternatives
4. Work Plan Rationale
   - DQO needs
   - Work plan approach
5. RI/FS Tasks
6. Costs and Key Assumptions
7. Schedule
8. Project Management
   - Staffing
   - Coordination
9. References

Appendices

2.3.2 *Sampling and Analysis Plan (SAP)*

2.3.2.1 Purpose

The SAP consists of two parts: (1) a quality assurance project plan (QAPP) that describes the policy, organization, functional activities, and quality assurance and quality control protocols necessary to achieve DQOs dictated by the intended use of the data; and (2) the field sampling plan (FSP) that provides guidance for all fieldwork by defining in detail the sampling and data-gathering methods to be used on a project. The FSP should be written so that a field sampling team unfamiliar with the site would be able to gather the samples and field information required. Guidance for the selection and definition of field methods, sampling procedures, and custody can be acquired from the *Compendium of Superfund Field Operations Methods*, which is a compilation of demonstrated field techniques that have been used during remedial response activities at hazardous waste sites (U.S. EPA, September 1987, hereafter referred to as the *Compendium*). To the extent possible, procedures from this *Compendium* should be incorporated by reference. In addition, the FSP and QAPP should be submitted as a single document (although they may be bound separately to facilitate use of the FSP in the field). These efforts will streamline preparation of the document and reduce the time required for review.

The purpose of the SAP is to ensure that sampling data collection activities will be comparable to and compatible with previous data collection activities performed at the site while providing a mechanism for planning and approving field activities. The plan also serves as a basis for estimating costs of field efforts for inclusion in the work plan.

2.3.2.2 Plan Preparation and Responsibilities

Timing. A SAP is prepared for all field activities. Initial preparation takes place before any field activities begin, but the SAP may be amended or revised several times during the RI site characterization, treatability investigations, or during the FS as the need for field activities is reassessed and rescoped.

Preparation and Review. EPA, the states, PRPs, or the contractors conducting the work should prepare SAPs for all field activities performed. The lead agency's project officer must approve the SAP. Signatures on the title page of the plan usually show completion of reviews and approvals. Environmental sampling should not be initiated until the SAP has received the necessary approvals.[9] A suggested format for a SAP is listed in Table 2-4.

2.3.2.3 Field Sampling Plan Elements

The FSP consists of the six elements contained in Table 2-4. These elements are described more fully in Appendix B.

2.3.2.4 Quality Assurance Project Plan Elements

The QAPP should contain 14 elements. These elements are listed in Table 2-4 and described in Appendix B. The required information for each of the elements of a QAPP need not be generated each time a QAPP is prepared. Only those aspects of a QAPP that are specific to the site being investigated need to be explicitly described. If site-specific information is already contained in another document (e.g., the FSP) it need only be referenced. Similarly, any information contained in guidance documents such as the *DQO Guidance* should only be referenced and not repeated in the QAPP.

2.3.3 *Health and Safety Plan*

2.3.3.1 Purpose

Each remedial response plan will vary as to degree of planning, special training, supervision, and protective equipment needed. The health and safety plan

[9] Approval to conduct limited sampling (see Section 2.2.2.3) may be given as part of the interim authorization to prepare the work plans.

Table 2-4. Suggested Format for SAP (FSP and QAPP)

FSP

1. Site Background
2. Sampling Objectives
3. Sample Location and Frequency
4. Sample Designation
5. Sampling Equipment and Procedures
6. Sample Handling and Analysis

QAPP

Title Page
Table of Contents

1. Project Description
2. Project Organization and Responsibilities
3. QA Objectives for Measurement
4. Sampling Procedures
5. Sample Custody
6. Calibration Procedures
7. Analytical Procedures
8. Data Reduction, Validation, and Reporting
9. Internal Quality Control
10. Performance and Systems Audits
11. Preventative Maintenance
12. Data Assessment Procedures
13. Corrective Actions
14. Quality Assurance Reports

prepared to support the field effort must conform to the firm's or agency's health and safety program which must be in compliance with OSHA.

The site health and safety plan should be prepared concurrently with the SAP to identify potential problems early, such as the availability of adequately trained personnel and equipment. OSHA requires that the plan include maps and a detailed site description, results of previous sampling activities, and field reports. The plan preparer should review site information, along with proposed activities, and use professional judgment to identify potentially hazardous operations and exposures and prescribe appropriate protective measures. Appendix B of the *Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities* (NIOSH/OSHA/USCG/USEPA, 1985) provides an example of a generic format for a site health and safety plan that could be tailored to the needs of a specific employer or site.

2.3.3.2 Elements of the Health and Safety Plan

Each site health and safety plan should include, at a minimum, the 11 elements described in Appendix B of this guidance. The specific information required in a site health and safety plan is listed in 29 CFR 1910.120.

2.3.3.3 Site Briefings and Inspections

The OSHA regulation requires that safety briefings be held "prior to initiating any site activity and at such other times as necessary to ensure that employees are apprised of the site safety plan and that it is being followed."

The final component of site health and safety planning or informational programs is site auditing to evaluate compliance with and effectiveness of the site health and safety plan. The site health and safety officer or that person's designee should carry out the inspections.

2.3.4 Community Relations Plan

2.3.4.1 Purpose

The CRP documents the community relations history and the issues of community concern. It should describe the techniques that will be needed to achieve the objectives of the program. The plan is used by community relations staff, but it should also be used by federal and state agency technical staff members when planning technical work at the site.

2.3.4.2 Community Relations Plan Elements

Report preparation methods, the elements contained in a CRP, and a recommended format are included in *Community Relations in Superfund: A Handbook* (U.S. EPA, Interim, June 1988). This handbook also includes useful examples of community relations plans.

spatial variations in site characteristics and irregular geometries commonly found at actual sites. These models can also represent the actual configuration and effects of remedial actions on site conditions. Detailed mathematical models are sometimes appropriate for investigations in which detailed information on contaminant fate and transport is required.

Models also are useful for screening alternative remedial actions and may be used for a detailed analysis of alternatives. Deciding whether analytical or numerical models should be used and selecting appropriate models for either the remedial investigation or the feasibility study can be difficult. Modeling may not be needed if site conditions are well understood and if the potential effectiveness of different remedial actions can be easily evaluated. In selecting and applying models, it is important to remember that a model is an artificial representation of a physical system and is only one way of characterizing and assessing a site. A model cannot replace, nor can it be more accurate than, the actual site data. Additional information on determining contaminant fate and transport is provided in the "Superfund Exposure Assessment Manual" (U.S. EPA, April 1988).

3.4.2 Baseline Risk Assessment

3.4.2.1 General Information

Baseline risk assessments provide an evaluation of the potential threat to human health and the environment in the absence of any remedial action. They provide the basis for determining whether or not remedial action is necessary and the justification for performing remedial actions. The baseline risk assessment will also be used to support a finding of imminent and substantial endangerment if such a finding is required as part of an enforcement action. Detailed guidance on evaluating potential human health impacts as part of this baseline assessment is provided in the *Superfund Public Health Evaluation Manual (SPHEM)* (U.S. EPA, October 1986).[6] Guidance for evaluating ecological risks is currently under development within OSWER.

In general, the objectives of a baseline risk assessment may be attained by identifying and characterizing the following:

- Toxicity and levels of hazardous substances present in relevant media (e.g., air, ground water, soil, surface water, sediment, and biota)
- Environmental fate and transport mechanisms within specific environmental media such as physical, chemical, and biological degradation processes and hydrogeological conditions
- Potential human and environmental receptors
- Potential exposure routes and extent of actual or expected exposure
- Extent of expected impact or threat; and the likelihood of such impact or threat occurring (i.e., risk characterization)
- Level(s) of uncertainty associated with the above items

The level of effort required to conduct a baseline risk assessment depends largely on the complexity of the site. The goal is to gather sufficient information to adequately and accurately characterize the potential risk from a site, while at the same time conduct this assessment as efficiently as possible. Use of the conceptual site model developed and refined previously will help focus investigation efforts and, therefore, streamline this effort. Factors that may affect the level of effort required include:

- The number, concentration, and types of chemicals present
- Areal extent of contamination
- The quality and quantity of available monitoring data
- The number and complexity of exposure pathways (including the complexity of release sources and transport media)
- The required precision of sample analyses, which in turn depends on site conditions such as the extent of contaminant migration and the proximity, characteristics, and size of potentially exposed population(s)
- The availability of appropriate standards and/or toxicity data

3.4.2.2 Components of the Baseline Risk Assessment

The risk assessment process can be divided into four components:

- Contaminant identification
- Exposure assessment
- Toxicity assessment

[6] This guidance is currently undergoing revision.

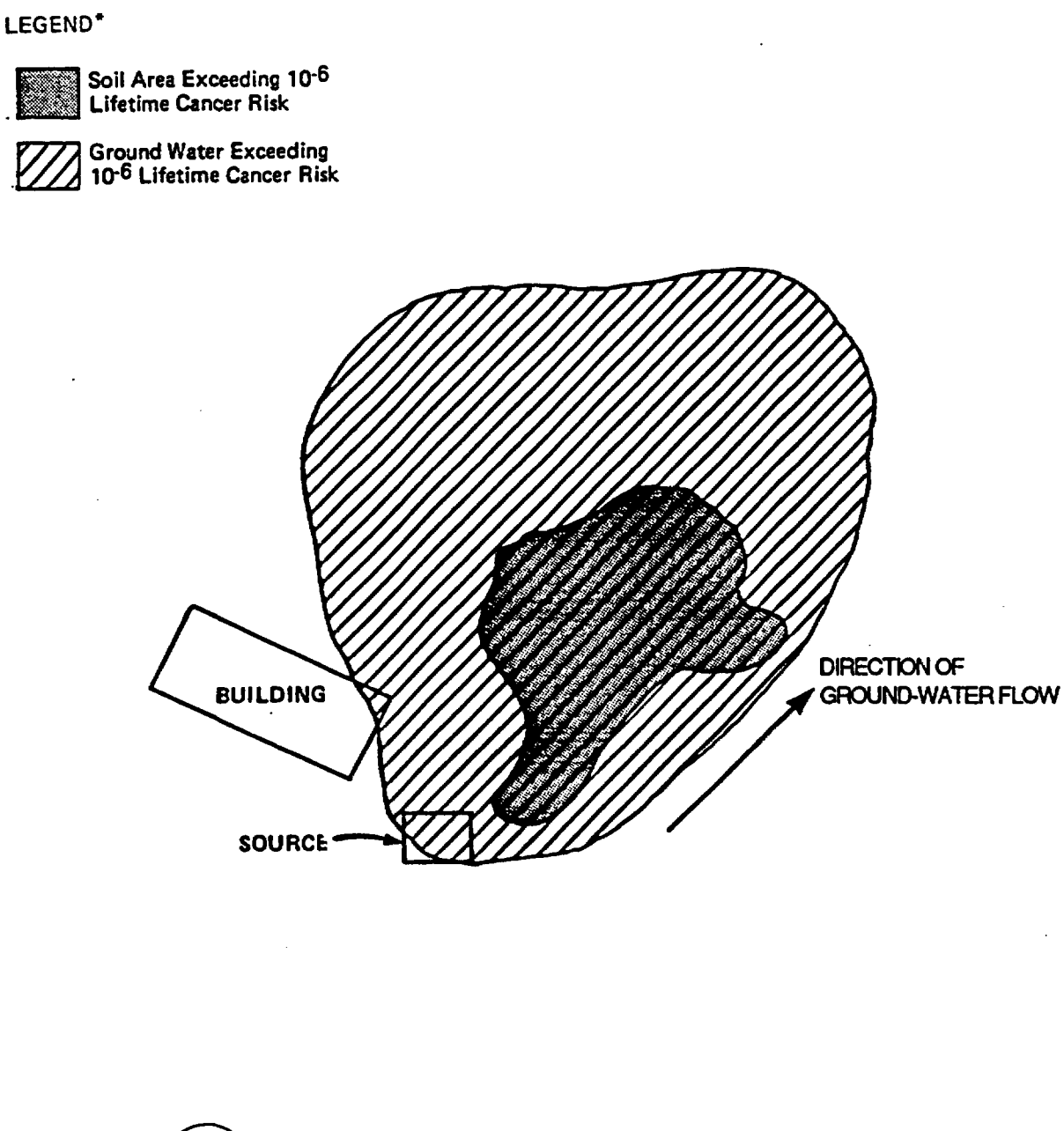


Figure 3-2. Representation of the areal extent of contamination.

Table 3-13. Suggested RI Report Format

Executive Summary

1. Introduction
   - 1.1 Purpose of Report
   - 1.2 Site Background
     - 1.2.1 Site Description
     - 1.2.2 Site History
     - 1.2.3 Previous Investigations
   - 1.3 Report Organization

2. Study Area Investigation
   - 2.1 Includes field activities associated with site characterization. These may include physical and chemical monitoring of some, but not necessarily all, of the following:
     - 2.1.1 Surface Features (topographic mapping, etc.) (natural and manmade features)
     - 2.1.2 Contaminant Source Investigations
     - 2.1.3 Meteorological Investigations
     - 2.1.4 Surface-Water and Sediment Investigations
     - 2.1.5 Geological Investigations
     - 2.1.6 Soil and Vadose Zone Investigations
     - 2.1.7 Ground-Water Investigations
     - 2.1.8 Human Population Surveys
     - 2.1.9 Ecological Investigations
   - 2.2 If technical memoranda documenting field activities were prepared, they may be included in an appendix and summarized in this report chapter.

3. Physical Characteristics of the Study Area
   - 3.1 Includes results of field activities to determine physical characteristics. These may include some, but not necessarily all, of the following:
     - 3.1.1 Surface Features
     - 3.1.2 Meteorology
     - 3.1.3 Surface-Water Hydrology
     - 3.1.4 Geology
     - 3.1.5 Soils
     - 3.1.6 Hydrogeology
     - 3.1.7 Demography and Land Use
     - 3.1.8 Ecology

4. Nature and Extent of Contamination
   - 4.1 Presents the results of site characterization, both natural chemical components and contaminants in some, but not necessarily all, of the following media:
     - 4.1.1 Sources (lagoons, sludges, tanks, etc.)
     - 4.1.2 Soils and Vadose Zone
     - 4.1.3 Ground Water
     - 4.1.4 Surface Water and Sediments
     - 4.1.5 Air

5. Contaminant Fate and Transport
   - 5.1 Potential Routes of Migration (i.e., air, ground water, etc.)
   - 5.2 Contaminant Persistence
     - 5.2.1 If they are appliable (i.e., for organic contaminants), describe estimated persistence in the study area environment and physical, chemical, and/or biological factors of importance for the media of interest.
   - 5.3 Contaminant Migration
     - 5.3.1 Discuss factors affecting contaminant migration for the media of importance (e.g., sorption onto soils, solubility in water, movement of ground water, etc.)
     - 5.3.2 Discuss modeling methods and results, if applicable.

6. Baseline Risk Assessment
   - 6.1 Human Health Evaluation
     - 6.1.1 Exposure Assessment
     - 6.1.2 Toxicity Assessment
     - 6.1.3 Risk Characterization
   - 6.2 Environmental Evaluation

Table 3-13 Continued

7. Summary and Conclusions
   - 7.1 Summary
     - 7.1.1 Nature and Extent of Contamination
     - 7.1.2 Fate and Transport
     - 7.1.3 Risk Assessment
   - 7.2 Conclusions
     - 7.2.1 Data Limitations and Recommendations for Future Work
     - 7.2.2 Recommended Remedial Action Objectives

Appendices

A. Technical Memoranda on Field Activities (if available)
B. Analytical Data and QA/QC Evaluation Results
C. Risk Assessment Methods

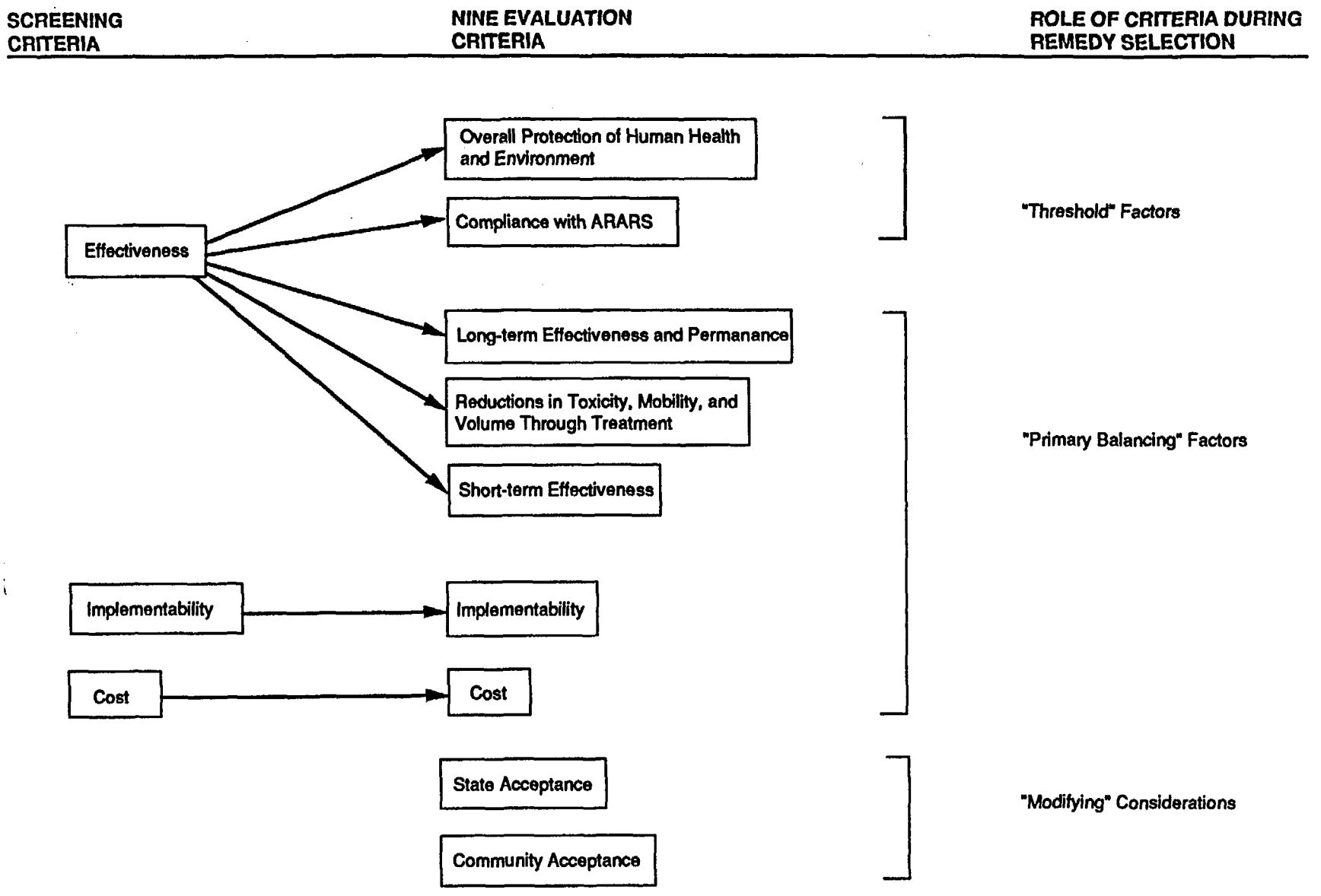


Figure 4-8. Relationship of Screening Criteria to the Nine Evaluation Criteria.

held to discuss community concerns and explain alternatives under consideration. Public officials should be briefed and press releases prepared describing the alternatives. Other activities identified in the community relations plan should be implemented.

The objective of community relations during the detailed analysis is to assist the community in understanding the alternatives and the specific considerations the lead agency must take into account in selecting an alternative. In this way, the community is prepared to provide meaningful input during the upcoming public comment period.

6.5 Reporting and Communication During Detailed Analysis

Once the draft RI/FS report is prepared, the lead agency obtains the support agency's review and concurrence, the public's review and comment, and local agency and PRP input, if appropriate. The RI/FS report also provides a basis for remedy selection by EPA (or concurrence on State and Federal facility remedy) and documents the development and analysis of alternatives. A suggested FS report format is given in Table 6-5.

Table 6-5. Suggested FS Report Format

Executive Summary

1. Introduction
   - 1.1 Purpose and Organization of Report
   - 1.2 Background Information (Summarized from RI Report)
     - 1.2.1 Site Description
     - 1.2.2 Site History
     - 1.2.3 Nature and Extent of Contamination
     - 1.2.4 Contaminant Fate and Transport
     - 1.2.5 Baseline Risk Assessment
2. Identification and Screening of Technologies
   - 2.1 Introduction
   - 2.2 Remedial Action Objectives –
     Presents the development of remedial action objectives for each medium of interest (i.e., ground water, soil, surface water, air, etc.). For each medium, the following should be discussed:
     - Contaminants of interest
     - Allowable exposure based on risk assessment (including ARARs)
     - Development of remediation goals
   - 2.3 General Response Actions –
     For each medium of interest, describes the estimation of areas or volumes to which treatment, containment, or exposure technologies may be applied.
   - 2.4 Identification and Screening of Technology Types and Process Options – For each medium of interest, describes:
     - 2.4.1 Identification and Screening of Technologies
     - 2.4.2 Evaluation of Technologies and Selection of Representative Technologies
3. Development and Screening of Alternatives
   - 3.1 Development of Alternatives –
     Describes rationale for combination of technologies/media into alternatives. Note: This discussion may be by medium or for the site as a whole.
   - 3.2 Screening of Alternatives (if conducted)
     - 3.2.1 Introduction
     - 3.2.2 Alternative 1
       - 3.2.2.1 Description
       - 3.2.2.2 Evaluation
     - 3.2.3 Alternative 2
       - 3.2.3.1 Description
       - 3.2.3.2 Evaluation
     - 3.2.4 Alternative 3
4. Detailed Analysis of Alternatives
   - 4.1 Introduction
   - 4.2 *Individual Analysis of Alternatives*
     - 4.2.1 Alternative 1
       - 4.2.1.1 Description
       - 4.2.1.2 Assessment
     - 4.2.2 Alternative 2
       - 4.2.2.1 Description
       - 4.2.2.2 Assessment
     - 4.2.3 Alternative 3
   - 4.3 Comparative Analysis

Bibliography

Appendices

Attachment III
Review and Oversight of the RI/FS

Review of Plans, Reports, and Records

EPA will review all RI/FS products which are submitted to the Agency as specified in the Work Plan or Administrative Order. PRPs should ensure that all plans, reports, and records are comprehensive, accurate, and consistent in content and format with the NCP and relevant EPA guidance. After this review process, EPA will either approve or disapprove the product. If the product is found to be unsatisfactory, EPA will notify the PRPs of the discrepancies or deficiencies and will require corrections within a specified time period.

- Project Plans

EPA will review all project plans that are submitted as deliverables in fulfillment of the Agreement. These plans include the Work Plan, the Sampling and Analysis Plan (including both the Field Sampling Plan and the Quality Assurance Project Plan), and the Health and Safety Plan. If the initial submittals are not sufficient in content or scope, the RPM will request that the PRPs submit revised document(s) for review. EPA does not "approve" the PRP's Health and Safety Plan but rather, it is reviewed to ensure the protection of public health and the environment. The PRP's Work Plan and Sampling and Analysis Plan, on the other hand, must be reviewed and approved prior to the initiation of field activities. Conditional approval to these plans may be provided in order to initiate field activities in a more timely manner.

The PRPs may be required to develop additional Work Plans or modify the initial Work Plan contained in or created pursuant to the Agreement. These changes may result from the need to: (1) re-evaluate the RI/FS activities due either to changes in or unexpected site conditions; (2) expand the initial Work Plan when additional detail is necessary; or (3) modify or add products to the Work Plan based on new information (e.g., a new population at risk). EPA will review and approve all Work Plans and/or modifications to Work Plans once they are submitted for review.

- Reports

PRPs will, at a minimum, submit monthly progress reports, technical memorandums or reports, and the draft and final RI/FS reports as required in the Agreement. To assist in the development of the RI/FS and review of documents, additional deliverables may be specified by the Region and included in the Agreement. These reports and deliverables will be reviewed by EPA to ensure that the activities specified in the Order and approved Work Plan are being properly implemented. These reports will generally be submitted according to the conditions and schedule set forth in the Agreement. Elements of the PRP reports are discussed below.

Monthly Progress Reports – The review of monthly progress reports is an important activity performed during oversight. These reports should provide sufficient detail to allow EPA to evaluate the past and projected progress of the RI/FS. PRPs should submit these written progress reports to the RPM. The report should describe the actions and decisions taken during the previous month and activities scheduled during the upcoming reporting period. In addition, technical data generated during the month (i.e., analytical results) should be appended to the report. Progress reports should also include a detailed statement of the manner and extent to which the procedures and dates set forth in the Agreement/ Work Plan are being met. Generally, EPA will determine the adequacy of the performance of the RI/FS by reviewing the following subjects discussed in progress reports:

- Technical Summary of Work

  The monthly report will describe the activities and accomplishments performed to date. This will generally include a description of all field work completed, such as sampling events and installation of wells; a discussion of analytical results received; a discussion of data review activities; and a discussion of the development, screening, and detailed analysis of alternatives. The report will also describe the activities to be performed during the upcoming month.

- Schedule

EPA will oversee PRP compliance with respect to those schedules specified in the Order. Delays, with the exception of those specified under the Force Majeure clause of the Agreement, may result in penalties, if warranted. The RPM should be immediately notified if PRPs cannot perform required activities or cannot provide the required deliverables in accordance with the schedule specified in the Work Plan. In addition, PRPs should notify the RPM when circumstances may delay the completion of any phase of the work or when circumstances may delay access to the site. PRPs should also provide to the RPM, in writing, the reasons for, and the anticipated duration of, such delays. Any measures taken or to be taken by the PRPs to prevent or minimize the delay should be described including the timetables for implementing such measures.

- Budget

The relationship of budgets to expenditures should be tracked where the RI/FS is funded with a financial mechanism established by the PRPs. If site activities require more funds than originally estimated, EPA must be assured that the PRPs are financially able to undertake additional expenditures. While EPA does not have the authority to review or approve a PRP budget, evaluating costs during the course of the RI/FS allows EPA to effectively monitor activity to ensure timely completion of RI/FS activities. If the PRPs run over budget, EPA must be assured that they can continue the RI/FS activities as scheduled. Therefore, if specified in the Agreement, PRPs should submit budget expenditures and cost overrun information to EPA. Budget reports need not present dollar amounts, but should indicate the relationship between remaining available funds and the estimate of the costs of remaining activities.

- Problems

Any problems that the PRPs encounter which could affect the satisfactory performance of the RI/FS should be brought to the immediate attention of EPA. Such problems may or may not be a force majeure event, or caused by a force majeure event. EPA will review problems and advise the PRPs accordingly. Problems which may arise include, but are not limited to:

- Delays in mobilization or access to necessary equipment;
- Unanticipated laboratory/analytical time requirements;
- Unsatisfactory QA/QC performance;
- Requirements for additional or more complex sampling;
- Prolonged unsatisfactory weather conditions;
- Unanticipated site conditions; and
- Unexpected, complex community relations activities.

Other Reports - All other reports, such as technical reports and draft and final RI/FS reports, should be submitted to EPA according to the schedule contained in the Order or the approved Work Plan. EPA will review and approve these reports as they are submitted. Suggested formats for the RI/FS reports are presented in the RI/FS Guidance.

- Records

PRPs should preserve all records, documents, and information of any kind relating to the performance of work at the site for a minimum of 6 years after completion of the work and termination of the Administrative Order. After the 6-year period, the PRPs should offer the records to EPA before their destruction.

Document control should be a key element of all recordkeeping. The following activities require careful recordkeeping and will be subject to EPA oversight:

Administration – PRP administrative activities should be accurately documented and recorded. Necessary precautions to prevent errors or the loss or misinterpretation of data should be taken. At a minimum, the following administrative actions should be documented and recorded:

- Contractor work plans, contracts, and change orders;
- Personnel changes;
- Communications between and among PRPs, the State, and EPA officials regarding technical aspects of the RI/FS;
- Permit application and award (if applicable); and
- Cost overruns.

Technical Analysis – Samples and data should be handled according to procedures set forth in the Sampling and Analysis Plan. Documentation

establishing adherence to these procedures should include:

- Sample labels;

- Shipping forms;

- Chain-of-custody forms; and

- Field log books.

All analytical data in the RI/FS process should be managed as set forth in the Sampling and Analysis Plan. Such analytical data may be the product of:

- Contractor laboratories;

- Environmental and public health studies; and

- Reliability, performance, and implementability studies of remedial alternatives.

Decision Making - Actions or communications among PRPs that involve decisions affecting technical aspects of the RI/FS should be documented. Such actions and communications include those of the project manager (or other PRP management entity), steering committees, or contractors.

- Administrative Record Requirements

Section 113(k) of CERCLA requires that the Agency establish an administrative record upon which the selection of a response action is based. A suggested list of documents which are most likely to be included in any adequate administrative record is provided in the memorandum entitled "Draft Interim Guidance on Administrative Records for Selection of CERCLA Response Actions" (June 23, 1988 - OSWER Directive No. 9833.3A). More detailed guidance will be forthcoming, including guidance provided in the revisions to the NCP. There are, however, certain details associated with compiling and maintaining an administrative record that are unique to PRP RI/FS activities.

EPA is responsible for compiling and maintaining the administrative record, and generating and updating an index. If EPA and the PRPs mutually agree, the PRPs may be allowed to house and maintain the administrative record file at or near the site; they may not, however, be responsible for the actual compilation of the record. Housing and maintaining the administrative record would include setting up a publicly accessible area at or near the site and ensuring that documents remain and are updated as necessary. EPA must always be responsible for deciding whether documents are included in the administrative record; transmitting records to the PRPs; and maintaining the index to the repository.

The information which may comprise the administrative record must be available to the public from the time an RI/FS Work Plan is approved by EPA. Once the Work Plan has been approved the PRPs must transmit to EPA, at reasonable, regular intervals, all of the information that is generated during the RI/FS that is related to selection of the remedy. The required documentation should be specified in the Administrative Order. The Agreement should also specify those documents generated prior to the RI/FS that must be obtained from the PRPs for inclusion in the record file. This may include any previous studies conducted under State or local authorities, management documents held by the PRPs such as hazardous waste shipping manifests, and other information about site characteristics or conditions not contained in any of the above documents.

Field Activities

- Field Inspections

Field inspections are an important oversight mechanism for determining the adequacy of the work performed. EPA will therefore conduct field inspections as part of its oversight responsibilities. The oversight inspections should be performed in a way that minimizes interference with PRP site activities or undue complication of field activities. EPA will take corrective steps, as described in Section VII and Attachment IV of this appendix, if unsatisfactory performance or other deficiencies are identified.

Several field-related tasks may be performed during oversight inspections. These tasks include:

On-site presence/inspection - As specified in Section 104(e)(3), EPA reserves the right to conduct on-site inspections at any reasonable time. EPA will therefore establish an on-site presence to assure itself of the quality of work being conducted by PRPs. At a minimum, field oversight will be conducted during critical times, such as the installation of monitoring wells and during sampling events. EPA will focus on whether the PRPs adhere to procedures specified in the SOW and Work Plan(s), especially those concerning QA/QC procedures. Further guidance regarding site characterization activities is presented in the RI/FS Guidance, the "Compendium of Superfund Field Operations Methods" (August 1987 - OSWER Directive No. 9355.0-141), the "RCRA Ground Water Technical Enforcement Guidance Document" (September 1986 - OSWER Directive No. 9950.1), the NEIC Manual for *Groundwater/ Subsurface Investigations at Hazardous Waste*

Sites (U.S. EPA, 1981c), and OWPE's forthcoming "Guidance on Oversight of Potentially Responsible Party Remedial Investigations and Feasibility Studies."

Collection and analysis of samples – EPA may collect a number of QA/QC samples including blank, duplicate, and split samples. The results of these sample analyses will be compared to the results of PRP analyses. This comparison will enable EPA to identify potential quality control problems and therefore help to evaluate the quality of the PRP investigation.

Environmental Monitoring – EPA may supplement any PRP environmental monitoring activity. Such supplemental monitoring may include air or water studies to determine additional migration of sudden releases that may have occurred as a result of site activities.

- QA/QC Audits

EPA may either conduct, or require the PRPs to conduct (if specified in the Agreement), laboratory audits to ensure compliance with proper QA/QC and analytical procedures, as specified in the Sampling and Analysis Plan. These audits will involve on-site inspections of laboratories used by PRPs and analyses of selected QA/QC samples. All procedures must be in accordance with those outlined in *The User's Guide to the Contract Laboratory Program*, (U.S. EPA, 1986) or otherwise specified in the Sampling and Analysis Plan.

- Chain-of-Custody

Chain-of-custody procedures will be evaluated by EPA. This evaluation will focus on determining if the PRPs and their contractors adhere to the procedures set forth in the Sampling and Analysis Plan. Proper chain-of-custody procedures are described in the *National Enforcement Investigation Center (NEIC) Policies and Procedures Manual*, (U.S. EPA, 1981b). Evaluation of chain-of-custody procedures will occur during laboratory audits as well as during on-site inspections of sampling activities.

Meetings

Meetings between EPA, the State, and PRPs should be held on a regular basis (as specified in the Agreement) and at critical times during the RI/FS. Such critical times may at a minimum include when the SOW and the Work Plan are reviewed, the RI is in progress and completed, remedial alternatives are developed and screened, detailed analysis of the alternatives is performed, and the draft and final RI/FS reports are submitted. These meetings will discuss overall progress, discrepancies in the work performed, problems encountered in the performance of RI/FS activities and their resolution, community relations, and other related issues and concerns. While meetings may be initiated by either the PRPs or EPA at any time, they will generally be conducted at the stages of the RI/FS listed below.

- Initiation of Activities

EPA, the State, and the PRPs may meet at various times before field activities begin to discuss the initial planning of the RI/FS. Meetings may be arranged to discuss, review, and approve the SOW; to develop the EPA/PRP Agreement; and to develop, review, and approve the Work Plan.

- Progress

EPA may request meetings to discuss the progress of the RI/FS. These meetings should be held at least quarterly and will focus on the items submitted in the monthly progress reports and the findings from EPA oversight activities. Any problems or deficiencies in the work will be identified and corrective measures will be requested (see Section VIII and Attachment IV of this appendix).

- Closeout

EPA may request a closeout meeting upon completion of the RI/FS. This meeting will focus on the review and approval of the final RI/FS report, termination of the RI/FS Agreement, and any final on-site activities which the PRPs may be required to perform. These activities may include maintaining the site and ensuring that fences and warning signs are properly installed. The transition to remedial design and remedial action will also be discussed during this meeting.

Special Studies

EPA may determine that special studies related to the PRP RI/FS are required. These studies can be conducted to verify the progress and results of RI/FS activities or to address a specific complex or controversial issue. Normally, special studies are performed by the PRPs; however, there may be cases in which EPA will want to conduct the independent studies. The PRPs should be informed of any such studies and given adequate time to provide necessary coordination of site personnel and resources. If not provided for in the Agreement, modifications to the Work Plan may be required.

Appendix B
Elements of RI/FS Project Plans

I. Elements of a Work Plan[1]

Introduction – A general explanation of the reasons for the RI/FS and the expected results or goals of the RI/FS process are presented.

Site Background and Physical Setting – The current understanding of the physical setting of the site, the site history, and the existing information on the condition of the site are described. (See Section 2.2.2.1.)

Initial Evaluation – The conceptual site model developed during scoping is presented, describing the potential migration and exposure pathways and the preliminary assessment of human health and environmental impacts. (See Section 2.2.2.2).

Work Plan Rationale – Data requirements for both the risk assessment and the alternatives evaluation identified during the formulation of the DQOs are documented, and the work plan approach is presented to illustrate how the activities will satisfy data needs.

RI/FS Tasks – The tasks to be performed during the RI/FS are presented. This description incorporates RI site characterization tasks identified in the QAPP and the FSP, the data evaluation methods identified during scoping (see Section 2.2.9), and the preliminary determination of tasks to be conducted after site characterization (see Section 2.2.7 of this guidance).

II. Standard Federal-Lead RI/FS Work Plan Tasks

Task 1. Project Planning (Project Scoping)

This task includes efforts related to initiating a project after the SOW is issued. The project planning task is defined as complete when the work plan and supplemental plans are approved (in whole or in part). The following typical elements are included in this task:

- Work plan memorandum
- Kickoff meeting (RI/FS brainstorming meeting)
- Site visit/meeting
- Obtaining easements/permits/site access
- Site reconnaissance and limited field investigation
- Site survey[2]/topographic map/review of existing aerial photographs
- Collection and evaluation of existing data
- Development of conceptual site model
- Identification of data needs and DQOs
- Identification of preliminary remedial action objectives and potential remedial alternatives
- Identification of treatability studies that may be necessary
- Preliminary identification of ARARs
- Preparation of plans (e.g., work plan, health and safety plan, QAPP, FSP)
- Initiation of subcontract procurement
- Initiation of coordination with analytical laboratories (CLP and non-CLP)
- Task management and quality control

Task 2. Community Relations

This task incorporates all efforts related to the preparation and implementation of the community relations plan for the site and is initiated during the scoping process. It includes time expended by both technical and community relations personnel. This task ends when community relations work under Task

[1] These elements are required in a work plan but do not necessarily represent the organization of a work plan.

[2] A site survey may be conducted during project planning or may occur during the field investigation task but should not occur in both.

12 is completed, but the task does not include work on the responsiveness summary in the ROD (see Task 12). The following are typical elements included in this task:

- Conducting community interviews
- Preparing a community relations plan
- Preparing fact sheets
- Providing public meeting support
- Providing technical support for community relations
- Implementing community relations
- Managing tasks and conducting quality control

Task 3. Field Investigation

This task involves efforts related to fieldwork in conducting the RI. It includes the procurement of subcontractors related to field efforts. The task begins when any element, as outlined in the work plan, is approved (in whole or in part) and fieldwork is authorized.[3] Field investigation is defined as complete when the contractor and subcontractors are demobilized from the field. The following activities are typically included in this task:

- Procurement of subcontracts
- Mobilization
- Media sampling
- Source testing
- Geology/hydrogeological investigations
- Geophysics
- Site survey/topographic mapping (if not performed in project planning task)
- Field screening/analyses
- Procurement of subcontractors
- RI waste disposal
- Task management and quality control

Task 4. Sample Analysis/Validation

This task includes efforts relating to the analysis and validation of samples after they leave the field. Separate monitoring of close support laboratories may be required. Any efforts associated with laboratory procurement are also included in this task. The task ends on the date that data validation is complete. The following typical activities are usually included in this task:

- Sample management
- Non-CLP analyses
- Use of mobile laboratories
- Data validation
- Testing of physical parameters
- Task management and quality control

Task 5. Data Evaluation

This task includes efforts related to the analysis of data once it has been verified that the data are of acceptable accuracy and precision. The task begins on the date that the first set of validated data is received by the contractor project team and ends during preparation of the RI report when it is deemed that no additional data are required. The following are typical activities:

- Data evaluation
- Data reduction and tabulation
- Environmental fate and transport modeling/evaluation
- Task management and quality control

Task 6. Assessment of Risks

This task includes efforts related to conducting the baseline risk assessment. The task will include work to assess the potential human health and environmental risks associated with the site. Work will begin during the RI and is completed once the baseline risk assessment is completed.[4] The following are typical activities:

- Identification of contaminants of concern (or indicator chemicals)
- Exposure assessment (including any modeling performed specifically for this function)
- Toxicity assessment
- Risk characterization
- Task management and quality control

[3] Note that limited fieldwork during project scoping may be authorized as part of the work assignment to prepare the RI/FS work plan.

[4] Limited efforts to assess potential human health and environmental risks are, to some extent, initiated during scoping when the conceptual site model is being developed.

Task 7. Treatability Study/Pilot Testing

This task includes efforts to prepare and conduct pilot, bench, and treatability studies. This task begins with the development of work plans for conducting the tests and is complete once the report has been completed. The following are typical activities:

- Work plan preparation or work plan amendment
- Test facility and equipment procurement
- Vendor and analytical service procurement
- Equipment operation and testing
- Sample analysis and validation
- Evaluation of results
- Report preparation
- Task management and quality control

Task 8. Remedial Investigation Reports

This task covers all efforts related to the preparation of the findings once the data have been evaluated under Tasks 5 and 6. The task covers all draft and final RI reports as well as task management and quality control. The task ends when the last RI document is submitted by the contractor to EPA. The following are typical activities:

- Preparation of a preliminary site characterization summary (see Section 3.7.2 of this guidance)
- Data presentation (formatting tables, preparing graphics)
- Writing the report
- Reviewing and providing QC efforts
- Printing and distributing the report
- Holding review meetings
- Revising the report on the basis of agency comments
- Providing task management and control

Task 9. Remedial Alternatives Development/Screening

This task includes efforts to select the alternatives to undergo full evaluation. The task is initiated once sufficient data are available to develop general response actions and begin the initial evaluation of potential technologies. This task is defined as complete when a final set of alternatives is chosen for detailed evaluation. The following are typical activities:

- Identifying/screening potential technologies
- Assembling potential alternatives
- Identifying action-specific ARARs
- Evaluating each alternative on the basis of screening criteria (effectiveness, implementability, cost)
- Reviewing and providing QC of work effort
- Preparing the report or technical memorandum
- Holding review meetings
- Refining the list of alternatives to be evaluated

Task 10. Detailed Analysis of Remedial Alternatives

This task applies to the detailed analysis and comparison of alternatives. The evaluation activities include performing detailed human health, environmental, and institutional analyses. The task begins when the alternatives to undergo detailed analysis have been identified and agreed upon and ends when the analysis is complete. The following are typical activities:[5]

- Refinement of alternatives
- Individual analysis against the criteria
- Comparative analysis of alternatives against the criteria
- Review of QC efforts
- Review meetings
- Task management and QC

Task 11. Feasibility Study (or RI/FS) Reports

Similar to the RI reports task, this task is used to report FS deliverables. However, this task should be used in lieu of the RI reports task to report costs and schedules for combined RI/FS deliverables. The task ends when the FS (or RI/FS) is released to the public. The following are typical activities:

[5] State and community acceptance will be evaluated by the lead agency during remedy selection.

- Presenting data (formatting tables, preparing graphics)
- Writing the report
- Printing and distributing the report
- Holding review meetings
- Revising the report on the basis of agency comments
- Providing task management and quality control

Task 12. Post RI/FS Support

This task includes efforts to prepare the proposed plan, the responsiveness summary, support the ROD, conduct any predesign activities, and close out the work assignment. All activities occurring after the release of the FS to the public should be reported under this task. The following are typical activities:

- Preparing the predesign report
- Preparing the conceptual design
- Attending public meetings
- Writing and reviewing the responsiveness summary
- Supporting ROD preparation and briefings
- Reviewing and providing QC of the work effort
- Providing task management and QC

Task 13. Enforcement Support

This task includes efforts during the RI/ FS associated with enforcement aspects of the project. Activities vary but are to be associated with efforts related to PRPs. The following are typical activities:

- Reviewing PRP documents
- Attending negotiation meetings
- Preparing briefing materials
- Assisting in the preparation of ROD
- Providing task management and QC

Task 14. Miscellaneous Support

This task is used to report on work that is associated with the project but is outside the normal RI/FS scope of work. Activities will vary but include the following:

- Specific support for coordination with and review of ATSDR activities and reports
- Support for review of special State or local projects

The following are some specific comments applicable to the 14 tasks described above:

- All standard tasks or all work activities under each task need not be used for every RI/FS. Only those that are relevant to a given project should be used.
- Tasks include both draft and final versions of deliverables unless otherwise noted.
- The phases of a task should be reported in the same task (e.g., field investigation Phase I and Phase II will appear as one field investigation task).
- If an RI/FS is divided into distinct operable units, each operable unit should be monitored and reported on separately. Therefore, an RI/FS with several operable units may, in fact, have more than 15 tasks, although each of the tasks will be one of the 15 standard tasks.
- Costs associated with project management and technical QA are included in each task.
- Costs associated with procuring subcontractors are included in the task in which the subcontractor will perform work (not the project planning task).
- Lists of standard tasks define the minimum level of reporting. For federal-lead tasks, some RPMs and contractors currently report progress in a more detailed fashion and may continue to do so as long as activities are associated with standard tasks.

III. Elements of a Quality Assurance Project Plan

Title Page – At the bottom of the title page, provisions should be made for the signatures of approving personnel. As a minimum, the QAPP must be approved by the following:

- Subcontractor's project manager (if a subcontractor is used)
- Subcontractor's QA manager (if a subcontractor is used)
- Contractor's project manager (if applicable)

- Contractor's QA manager (if applicable)
- Lead agency's project officer
- Lead agency's QA officer (if applicable)

Provision should be made for the approval or review of others (e.g., regional laboratory directors), if applicable.

Table of Contents – The table of contents will include an introduction, a serial listing of the 16 QAPP elements, and a listing of any appendixes that are required to augment the QAPP. The end of the table of contents should include a list of the recipients of official copies of the QAPP.

Project Description – The introduction to the project description consists of a general paragraph identifying the phase of the work and the general objectives of the investigation. A description of the location, size, and important physical features of the site such as ponds, lagoons, streams, and roads should be included (a figure showing the site location and layout is helpful). A chronological site history including descriptions of the use of the site, complaints by neighbors, permitting, and use of chemicals needs to be provided along with a brief summary of previous sampling efforts and an overview of the results. Finally, specific project objectives for this phase of data gathering need to be listed, and ways in which the data will be used to address each of the objectives must be identified. **Those items above that are also included in the work plan need not be repeated in the QAPP and, instead, may be incorporated by reference.**

Project Organization and Responsibilities – This element identifies key personnel or organizations that are necessary for each activity during the study. A table or chart showing the organization and line of authority should be included. When specific personnel cannot be identified, the organization with the responsibility should be listed.

QA Objectives for Measurement – For individual matrix groups and parameters, a cooperative effort should be undertaken by the lead agency, the principal engineering firm, and the laboratory staff to define what levels of quality should be required for the data. These QA objectives will be based on a common understanding of the intended use of the data, available laboratory procedures, and available resources. The field blanks and duplicate field sample aliquots to be collected for QA purposes should be itemized for the matrix groups identified in the project description.

The selection of analytical methods requires a familiarity with regulatory or legal requirements concerning data usage. Any regulations that mandate the use of certain methods for any of the sample matrices and parameters listed in the project description should be specified.

The detection limits needed for the project should be reviewed against the detection limits of the laboratory used. Special attention should be paid to the detection limits provided by the laboratory for volatile organic compounds, because these limits are sometimes insufficient for the analysis of drinking water. Detection limits may also be insufficient to assess attainment of ARARs. For Federal-lead projects, if QA objectives are not met by CLP RASs, then one or more CLP SASs can be written.

Quantitative limits should be established for the following QA objectives:

1. Accuracy of spikes, reference compounds
2. Precision
3. Method detection limits

These limits may be specified by referencing the SOW for CLP analysis, including SAS requests, in an appendix and referring to the appendix or owner/operator manuals for field equipment.

Completeness, representativeness, and comparability are quality characteristics that should be considered during study planning. Laboratories should provide data that meet QC acceptance criteria for 90 percent or more of the requested determinations. Any sample types, such as control or background locations, that require a higher degree of completeness should be identified. "Representativeness" of the data is most often thought of in terms of the collection of representative samples or the selection of representative sample aliquots during laboratory analysis. "Comparability" is a consideration for planning to avoid having to use data gathered by different organizations or among different analytical methods that cannot reasonably be compared because of differences in sampling conditions, sampling procedures, etc.

Sampling Procedures – These procedures append the site-specific sampling plan. Either the sampling plan or the analytical procedures element may document field measurements or test procedures for hydrogeological investigations.

For each major measurement, including pollutant measurement systems, a description of the sampling procedures to be used should be provided. Where applicable, the following should be included:

- A description of techniques or guidelines used to select sampling sites

- A description of the specific sampling procedures to be used
- Charts, flow diagrams, or tables delineating sampling program
- A description of containers, procedures, reagents, and so forth, used for sample collection, preservation, transport, and storage
- A discussion of special conditions for the preparation of sampling equipment and containers to avoid sample contamination
- A description of sample preservation methods
- A discussion of the time considerations for shipping samples promptly to the laboratory
- Examples of the custody or chain-of-custody procedures and forms
- A description of the forms, notebooks, and procedures to be used to record sample history, sampling conditions, and analyses to be performed

The DQO document described above can also be incorporated by reference in this section. In addition, the *Compendium of Superfund Field Operations Methods* (U.S. EPA, September 1987) contains information pertinent to this section and can be incorporated by reference.

Sample Custody – Sample custody is a part of any good laboratory or field operation. If samples were needed for legal purposes, chain-of-custody procedures, as defined by the *NEIC Policies and Procedures* (U.S. EPA, June 1985), would be used. Custody is divided into three parts:

- Sample collection
- Laboratory
- Final evidence files

The QAPP should address all three areas of custody and should refer to the *User's Guide to the Contract Laboratory Program* (U.S. EPA, December 1986) and Regional guidance documents for examples and instructions. For federal-lead projects, laboratory custody is described in the CLP SOW; this may be referenced. Final evidence files include all originals of laboratory reports and are maintained under documented control in a secure area.

A sample or an evidence file is under custody if:

- It is in your possession.
- It is in your view, after being in your possession.
- It was in your possession and you placed it in a secure area.
- It is in a designated secure area.

A QAPP should provide examples of chain-of-custody records or forms used to record the chain of custody for samples, laboratories, and evidence files.

Calibration Procedures – These procedures should be identified for each parameter measured and should include field and laboratory testing. The appropriate standard operating procedures (SOPs) should be referenced, or a written description of the calibration procedures to be used should be provided.

Analytical Procedures – For each measurement, either the applicable SOP should be referenced or a written description of the analytical procedures to be used should be provided. Approved EPA procedures or their equivalent should be used.

Data Reduction, Validation, and Reporting – For each measurement, the data reduction scheme planned for collected data, including all equations used to calculate the concentration or value of the measured parameter, should be described. The principal criteria that will be used to validate the integrity of the data during collection and reporting should be referenced.

Internal Quality Control – All specific internal QC methods to be used should be identified. These methods include the use of replicates, spike samples, split samples, blanks, standards, and QC samples. Ways in which the QC information will be used to qualify the field data should be identified.

Performance and Systems Audits – The QAPP should describe the internal and external performance and systems audits that will be required to monitor the capability and performance of the total measurement system. The current *CLP Invitation for Bids* for organic and inorganic analyses may be referenced for CLP RAS performance and systems audits. The *Compendium of Superfund Field Operations Methods* (U.S. EPA, September 1987) may be referenced for routine fieldwork.

The systems audits consist of the evaluation of the components of the measurement systems to determine their proper selection and use. These audits include a careful evaluation of both field and laboratory QC procedures and are normally performed before or shortly after systems are operational. However, such audits should be performed on a regular schedule during the lifetime of the project or continuing operation. An onsite systems audit may be required for formal laboratory certification programs.

After systems are operational and are generating data, performance audits are conducted periodically to determine the accuracy of the total measurement system or its component parts. The QAPP should include a schedule for conducting performance audits for each measurement parameter. Laboratories may be required to participate in the analysis of performance evaluation samples related to specific projects. Project plans should also indicate, where applicable, scheduled participation in all other interlaboratory performance evaluation studies.

In support of performance audits, the environmental monitoring systems and support laboratories provide necessary audit materials and devices, as well as technical assistance. These laboratories conduct regular interlaboratory performance tests and provide guidance and assistance in the conduct of systems audits. The laboratories should be contacted if assistance is needed in the above areas.

Preventive Maintenance – A schedule should be provided of the major preventative maintenance tasks that will be carried out to minimize downtime of field and laboratory instruments. Owner's manuals may be referenced for field equipment.

Specific Routine Procedures Used to Assess Data (Precision, Accuracy, and Completeness) – The precision and accuracy of data must be routinely assessed for all environmental monitoring and measurement data. The QAPP should describe specific procedures to accomplish this assessment. If enough data are generated, statistical procedures may be used to assess the precision, accuracy, and completeness. If statistical procedures are used, they should be documented.

Corrective Actions – In the context of QA, corrective actions are procedures that might be implemented on samples that do not meet QA specifications. Corrective actions are usually addressed on a case-by-case basis for each project. The need for corrective actions is based on predetermined limits for acceptability. Corrective actions may include resampling, reanalyzing samples, or auditing laboratory procedures. The QAPP should identify persons responsible for initiating these actions, procedures for identifying and documenting corrective actions, and procedures for reporting and followup.

Quality Assurance Project Plans – QAPPs should identify the method to be used to report the performance of measurement systems and data quality. This reporting should include results of performance audits, results of systems audits, and significant QA problems encountered, along with recommended solutions. The RI report should include a separate QA section that summarizes the data quality.

IV. Elements of a Field Sampling Plan[6]

Site Background – If the analysis of existing data is not included in the work plan or QAPP, it must be included in the FSP. This analysis would include a description of the site and surrounding areas and a discussion of known and suspected contaminant sources, probable transport pathways, and other information about the site. The analysis should also include descriptions of specific data gaps and ways in which sampling is designed to fill those gaps. Including this discussion in the FSP will help orient the sampling team in the field.

Sampling Objectives – Specific objectives of a sampling effort that describe the intended uses of data should be clearly and succinctly stated.

Sample Location and Frequency – This section of the sampling plan identifies each sample matrix to be collected and the constituents to be analyzed. A table may be used to clearly identify the number of samples to be collected along with the appropriate number of replicates and blanks. A figure should be included to show the locations of existing or proposed sample points.

Sample Designation – A sample numbering system should be established for each project. The sample designation should include the sample or well number, the sampling round, the sample matrix (e.g., surface soil, ground water, soil boring), and the name of the site.

Sampling Equipment and Procedures – Sampling procedures must be clearly written. Step-by-step instructions for each type of sampling are necessary to enable the field team to gather data that will meet the DQOs. A list should include the equipment to be used and the material composition (e.g., Teflon, stainless steel) of the equipment along with decontamination procedures.

Sample Handling and Analysis – A table should be included that identifies sample preservation methods, types of sampling jars, shipping requirements, and holding times. SAS requests and CLP SOWs may be referenced for some of this information.

Examples of paperwork and instructions for filling out the paperwork should be included. Use of the CLP requires that traffic reports, chain-of-custody forms, SAS packing lists, and sample tags be filled out for each sample. If other laboratories are to be used, the specific documentation required should be

[6] Field sampling plans are site-specific and may include additional elements.

identified. Field documentation includes field notebooks and photographs.

Provision should be made for the proper handling and disposal of wastes generated onsite. The site-specific procedures need to be described to prevent contamination of clean areas and to comply with existing regulations.

V. Elements of a Health and Safety Plan

1. The name of a site health and safety officer and the names of key personnel and alternates responsible for site safety and health
2. A health and safety risk analysis for existing site conditions, and for each site task and operation
3. Employee training assignments
4. A description of personal protective equipment to be used by employees for each of the site tasks and operations being conducted
5. Medical surveillance requirements
6. A description of the frequency and types of air monitoring, personnel monitoring, and environmental sampling techniques and instrumentation to be used
7. Site control measures
8. Decontamination procedures
9. Standard operating procedures for the site
10. A contingency plan that meets the requirements of 29 CFR 1910.120(l)(1) and (l)(2)
11. Entry procedures for confined spaces